



Safety manual for hearing instruments



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Safety information

This safety manual provides safety information and other important information about your hearing instruments. It covers several instrument types and optional features.

- Refer to the user guide of your hearing instruments, to check the instrument type and the activated features.

Intended use

Hearing instruments are intended to improve the hearing of hearing impaired persons. Diagnosis and prescription of a hearing instrument must be performed by hearing health specialists, e.g. acousticians, audiologists or ENT doctors.

Use the hearing instruments and accessories only as described in the respective user guides.

Explanation of symbols

Symbols used in this document



Points out a situation that could lead to serious, moderate, or minor injuries.



Indicates possible property damage.



Information and warnings for children with hearing instruments.

Symbols on the device or packaging



CE compliance label, confirms compliance with certain European Directives, refer to section "Conformance information".



EMC and radio communications compliance label Australia, refer to section "Conformance information".



Optional symbol for custom models with wireless functionality.



Indicates the legal manufacturer of the device.



Do not dispose of the device with general domestic waste. Read more in section "Disposal information".



Read and follow the instructions in the user guide.

General warnings



WARNING

Risk of impairing the residual hearing of the user.

- Use only hearing instruments that have been fitted especially for your needs.



WARNING

Risk of injury!

- Do not use obviously damaged devices and return them to point of sale.

**WARNING**

Note that any unauthorized changes to the product may cause damage to the product or cause injury.

- Use only approved parts and accessories. Ask your Hearing Care Professional for support.

**WARNING**

Your hearing instruments may reduce certain background sounds, potentially also traffic or warning signals.

**WARNING**

Risk of explosion!

- Do not use your hearing instruments in explosive atmospheres (e. g. in mining areas).

**WARNING**

Choking hazard!

Your hearing instruments contain small parts which can be swallowed.

- Keep hearing instruments, batteries and accessories out of reach of children and mentally disabled persons.
- If parts have been swallowed consult a physician or hospital immediately.

If you have hearing instruments that are intended for the fitting of infants, small children, or mentally disabled persons, refer also to section "For infants, small children and mentally disabled persons".

**NOTICE**

- ▶ Protect your hearing instruments from high humidity. Do not wear them in the shower or when you apply make-up, perfume, aftershave, hairspray or suntan lotion.

**NOTICE**

Only use zinc-air batteries or nickel-metal hydride (NiMH) rechargeable batteries.

Do not use e.g. silver-zinc or lithium-ion rechargeable batteries.

**NOTICE**

Leaking batteries damage the hearing instruments.

- ▶ Turn the hearing instruments off when not in use to preserve the battery.
- ▶ Remove batteries when the instruments are not in use for a prolonged period of time.

**NOTICE**

- ▶ Protect your hearing instruments from extreme heat. Do not expose them to direct sunlight.

**NOTICE**

- ▶ Do not dry your hearing instruments in the microwave oven.



NOTICE

Different types of strong radiation, e. g. during X-ray or MRI head examinations, may damage hearing instruments.

- ▶ Do not wear the hearing instruments during these or similar procedures.

Weaker radiation, e. g. from radio equipment or airport security, does not damage the hearing instruments.

Contraindications



WARNING

Consult a Hearing Care Professional if you experience any unusual side effects like skin irritation, excessive accumulation of ear wax, dizziness, change in your hearing, or if you think there may be a foreign object in your ear canal.



WARNING

A Hearing Care Professional should advise a prospective hearing instrument user to consult a licensed physician before using the hearing instrument if the Hearing Care Professional determines that the prospective user has any of the following conditions:

- ▶ Visible congenital or traumatic deformity of the ear.
- ▶ History of active drainage from the ear within the previous 90 days.
- ▶ History of sudden or rapidly progressive hearing loss within the previous 90 days.
- ▶ Acute or chronic dizziness.
- ▶ Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- ▶ Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1,000 Hz, and 2,000 Hz.
- ▶ Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- ▶ Pain or discomfort in the ear.

For hearing instruments with wireless functionality



In some countries restrictions for the usage of wireless equipment exist.

- Refer to local authorities for further information.



WARNING

Risk of affecting electronic equipment!

- In areas where the use of electronics or wireless devices are restricted, verify if your device has to be turned off.



NOTICE

Your hearing instruments are designed to comply with international standards on electromagnetic compatibility but interference with nearby electronic devices could occur. In this case, move away from the source of interference.

For hearing instruments with tinnitus noiser function

Your hearing instrument may be equipped with a tinnitus noiser. The use of the tinnitus noiser should be only on the advice and in consultation with your Hearing Care Professional.



WARNING

Risk of further impairment to the user's hearing health.

The volume of the tinnitus noiser can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time.

- ▶ The tinnitus noiser should never be used at uncomfortable levels.

For hearing instruments with AutoPhone magnet



WARNING

Risk of affecting life support systems!

- ▶ Use a magnet only when it is a safe distance away from life support systems, such as pacemakers or magnetic valves. For example, the safe distance between pacemaker and magnet should be at least 10 cm (4 inches).



NOTICE

Magnets can disturb electrical devices and delete stored data.

- Keep magnets away from computers, monitors, television sets, storage media and other electronic equipment/devices.

For hearing instruments with a magnet in the battery compartment



WARNING

Risk of interference with active and non-active implants!

If you wear an active or a non-active implant, e.g. a brain implant:

- Prior to use, have the electromagnetic compatibility verified.
Consult the physician that implanted the device before using your hearing instruments.
- Keep a safe distance of about 1.6 inches (4 cm) between the implant and hearing instruments.

BTE or RIC or custom models

BTE models

Instruments that are worn behind the ear and that have a tube.



CAUTION

Risk of injury!

- ▶ Always wear the tube with an ear piece.
- ▶ Make sure that the ear piece is completely attached.

RIC models

The receiver is placed within the ear canal and connected to the instrument via a receiver cable.



CAUTION

Risk of injury!

- ▶ Always wear the receiver cable with an ear piece.
- ▶ Make sure that the ear piece is completely attached.



NOTICE

- ▶ Do not pull the receiver connection as this could damage your hearing instruments.



Custom models

There is no additional safety information that applies for custom models only.

For infants, small children and mentally disabled persons

There are special hearing instruments for the fitting of infants and small children. Ask your Hearing Care Professional for further information.



WARNING



Choking hazard!

Your hearing instruments contain small parts which can be swallowed.

- ▶ Ensure adequate supervision if infants, small children or mentally disabled persons need to wear hearing instruments.
- ▶ Check the completeness of the hearing instruments regularly.
- ▶ Ensure that your child or the mentally disabled person does not detach the hearing instrument from the earmold.
- ▶ Consult your Hearing Care Professional if the housing is deformed.
- ▶ Keep the battery compartment locked. Verify the proper function of the locking mechanism.
- ▶ Keep batteries and accessories out of children's or mentally disabled person's reach.
- ▶ If swallowed consult a physician or a hospital immediately.

When using remote control apps

When using an app for controlling hearing instruments:



WARNING

Risk of hearing damage!

The device with the app for controlling hearing instruments generates short control signals which may be audible. If the device running the app has a very high audio output there is the risk of hearing damage.

While using the app:

- ▶ Do not hold the loudspeaker of the device to your ears or the ears of others.
- ▶ Do not use the device with headphones, headsets or other audio playback devices.

For Hearing Care Professionals



WARNING

For hearing instruments with an output sound pressure level of 132 dB SPL or more:

Risk of impairing the residual hearing of the user.

- Take special care when fitting this instrument.

Tinnitus noiser function

The target population is primarily the adult population over 21 years of age. The patient may have some control of the level or volume of the signal and the patient should discuss this adjustment as well as his or her comfort level and sound of the signal with their Hearing Care Professional.



WARNING

Risk of further impairment to the user's hearing health.

The volume of the tinnitus noiser can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time.

- Should the tinnitus noiser be set to such a level in the hearing instrument, advise the user of the maximum amount of time per day he or she should use the tinnitus noiser.

For example, occupational safety guidelines restrict continuous noise exposure of 80 dBA SPL to 8 hours per day.

- The tinnitus noiser should never be used at uncomfortable levels.

Important information

Transport and storage conditions

During extended periods of transport and storage, please observe the following conditions:

	Storage	Transport
Temperature	10 to 40 °C (50 to 104 °F)	-20 to 60 °C (-4 to 140 °F)
Relative humidity	10 to 80 %	5 to 90 %

For other parts, such as batteries, other conditions may apply.

Disposal information

- ▶ Recycle hearing instruments, accessories and packaging according to local regulations.
- ▶ To avoid environmental pollution, do not throw batteries into household trash.
- ▶ Recycle or dispose of batteries according to local regulations or return them to your Hearing Care Professional.

Conformance information

With the CE marking Sivantos declares conformity with the following European directives:

- 93/42/EEC concerning medical devices
- 99/5/EC (R&TTE) concerning radio and telecommunications equipment (only for products with wireless functionality)
- 2011/65/EU RoHs concerning the restriction of hazardous substances

With the ACMA compliance mark  Sivantos declares conformity with the electromagnetic interference standards set by the Australian Communications and Media Authority (ACMA).

Devices with the FCC marking comply with the standards of the FCC regarding electromagnetic interference (only for products with wireless functionality).

Technical details

Operating frequency: $f_c = 3.28$ MHz

USA FCC ID: SGI-WL003BTE

Canada IC: 267AB-WL003BTE

Wireless platform, model: e2e 3.0

This Class B digital apparatus complies with Canadian ICES-003.

Changes or modifications made to this equipment not expressly approved by the legal manufacturer may void the FCC authorization to operate this equipment.

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada.

Operation is subject to the following conditions:

- this device may not cause harmful interference, and
- this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged

to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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